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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,873	03/23/2005	Brian J. Pelkey	P-5874	6408

7590 10/18/2006

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EXAMINER
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MACNEILL, ELIZABETH

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/528,873

Applicant(s)

PELKEY ET AL.

Examiner

Elizabeth R. MacNeill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 17 and 19-28 is/are rejected.
- 7) ☒ Claim(s) 13-16 and 18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-12,17, and 19-28 are rejected under 35 U.S.C. 102(b) as being anticipated by SCHOENFELD (US 5,181,912)

Regarding claims 1,24-26, and 28 Schoenfeld teaches a syringe assembly comprising: a syringe barrel (10) having an inside surface defining a chamber, an open end, and a distal end; a plunger rod (22) extending within said syringe barrel, said plunger rod including an elongate body portion defining a longitudinal axis, a stopper (44) at a distal end of said elongate body portion, a disc (52), and at least one axially extending recess formed by a pair of surfaces (14) radially displaced from the longitudinal axis of said elongate body portion, each of said surfaces defining at least one proximal tooth (Fig 18, 130) and at least one distal tooth (Fig 18, tooth distal of 130), said plunger rod being substantially immovable after performing a first retraction stroke in the direction of said open end, a first injection stroke in the direction of said distal end, a second retraction stroke in the direction of said open end and a second injection stroke in the direction of said distal end (Col 13, last full paragraph); and a locking element (40, Fig 10) slidably positioned within said recess, said locking element engaging (via 111) said inside surface of said syringe barrel such that said locking element is substantially immovable

in the direction of the open end of said syringe barrel, said locking element further being engageable with said at least one proximal tooth (via 89) during said first injection stroke of said plunger rod and said locking element being engageable with said at least one distal tooth (via 87) during said second injection stroke of said plunger rod. See Figures 13 and 18.

Regarding claims 2-4, and 17, said barrel further defines an annular ring (5) for limiting movement of said plunger rod in the direction of said open end.

Regarding claim 5, said at least one proximal tooth comprises a plurality of proximal teeth and said at least one distal tooth comprises a plurality of distal teeth (Fig 12)

Regarding claims 6 and 7, said at least one proximal tooth comprises three teeth and said at least one distal tooth comprises three teeth (Fig 32)

Regarding claim 8, said locking element is comprised of an integral, resilient metal structure, said locking element being positioned such that said plunger rod can be moved proximally with respect to said locking element (Col 16 line 51)

Regarding claim 9, said locking element includes one or more proximally extending barbs engaging said inside surface of said syringe barrel, and said locking element and stopper are positioned such that said plunger rod can be moved proximally with respect to said locking element (Fig 11)

Regarding claims 10-12,27 said locking element includes a body portion having a distal end and proximal end, said body portion of said locking element being generally V-shaped and engageable with each of said pair of surfaces (Fig 10)

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Regarding claims 19-23, the syringe further includes a needle (2) in fluid communication with said barrel, either removably or integrally connected to the distal end of the barrel and being either sharp or blunt.

3. Claims 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by KOSINSKI (US 4,961,728).

Regarding claims 24 and 25, Kosinski teaches a syringe barrel (20) having an annular ring (25); a plunger rod (33), a stopper (39), a disc (65), a first axially extending recess (35) defining a plurality of teeth (67), and a second recess defining at least one distal and at least one proximal tooth (67); and a locking element (50) being engagable with said teeth.

***Allowable Subject Matter***

4. Claims 13-16 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The following is a statement of reasons for the indication of allowable subject matter: Regarding claims 13-15, the prior art does not teach or suggest a plurality of radially extending walls that converge near said longitudinal axis and a first additional wall extending from one of said radially extending walls in a non-radial direction, said first additional wall defining one of said surfaces forming said recess, including a second additional wall extending from one of said radially extending walls, said second additional wall defining one of said surfaces forming said recess, wherein said second

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additional wall is substantially parallel to said first additional wall, when combined with the limitations of claim 1.

Regarding claim 16, the prior art does not teach or suggest that said elongate body portion of said plunger rod includes a first wall proximal to said stopper and a plurality of second walls projecting from a first side of first wall, two of said second walls defining said surfaces forming said recess when combined with the limitations of claim 1

Regarding claim 18, the prior art does not teach or suggest that said locking element has a longitudinal length substantially equal to said distance, when combined with the limitations of claims 17 and claim 1.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

*W. J. Little*  
*Mac Bell*  
*10/11/06*

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

*Kevin C. Sirmons*